BEFORE THE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MD 20852

DRAFT GUIDANCE FOR INDUSTRY BRIEF SUMMARY: DISCLOSING RISK INFORMATION IN CONSUMER-DIRECTED PRINT ADVERTISEMENTS

[Docket No. 2004D-0042]

COMMENTS OF THE
NEWSPAPER ASSOCIATION OF AMERICA

May 7, 2004

2004D-0042

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2004D-0042
Draft Guidance for Industry
Brief Summary: Disclosing Risk
Information in Consumer-Directed Print
Advertisements

These comments are submitted on behalf of the members of the Newspaper Association of America (NAA), the principal trade association representing daily newspapers. NAA represents more than 2,000 newspapers in the United States and Canada and its membership accounts for nearly 90 percent of U. S. daily newspaper circulation. NAA is pleased that FDA has carefully considered the changes to the brief summary requirement for print advertisements which NAA proposed in its Sept. 12, 2002, comments responding to FDA's request on how the agency can ensure that its regulations, guidances, policies and practices are in accordance with the First Amendment. In those comments, NAA urged the FDA to substantially reduce the required content of the brief summary in direct-to-consumer prescription drug print advertising in order to bring the FDA requirements within First Amendment limitations. As NAA noted in its comments, doing so would also enable consumers to more easily focus on the safety information relevant to their decision making without having to work through lengthy complicated information that is unlikely to influence their decision. Risk information conveyed under the existing brief summary requirement is directed primarily at health

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professionals in language that may be unfamiliar to most consumers and, consequently, is of little use to them.

NAA supports the approach FDA has proposed to adopt in the draft guidance to allow for meaningful alternatives to the inclusion of the entire brief summary in print advertising. As discussed in our prior comments, FDA's requirement that the brief summary be included in its entirety in print advertisement exceeds the limits of what is permissible under the First Amendment without providing any substantial benefits to health care professionals and patients in terms of useful and significant information.

The draft guidance provides for alternatives to the brief summary that are appropriately informative and protective of consumers while also being easily included in typical newspaper advertisements. The adoption of this guidance allowing for the use of such alternatives will expand the amount of useful and comprehensible information available to consumers regarding prescription drugs and will bring the FDA requirements for print advertisement within the bounds of what is permissible under the First Amendment. It will also have the benefit of reducing the inequities between print and broadcast media which FDA's existing policies have created in the area of direct-to-consumer prescription drug advertising.

NAA appreciates the opportunity to comment on this draft guidance and looks forward to working with advertisers and the FDA to fulfill the promise of more effective communication of risk information about prescription drugs to consumers through newspaper advertising.

Respectfully submitted,

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